

CLAIMS

What is claimed is:

1. A precursor composition for preparing a buffered dialysate, the precursor composition comprising citrate at a concentration ranging from about 20 to about 900 mEq/L; a buffer; water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; and at least one physiologically-acceptable cation.
2. The composition of claim 1 wherein the buffer comprises a buffering anion selected from acetate and lactate.
3. The composition of claim 1 wherein the buffer comprises a buffering anion selected from acetate and lactate at a concentration ranging from about 0.01 to about 150 mEq/L.
4. A precursor composition for preparing a buffered dialysate, the precursor composition comprising water; chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L; citrate at a concentration ranging from about 20 to about 900 mEq/L; at least one buffering anion selected from acetate and/or lactate at a concentration ranging from about 0.01 to about 150 mEq/L; and at least one physiologically-acceptable cation.
5. The precursor composition of claims 1-4 comprising citrate at a concentration ranging from about 70 to about 150 mEq/L.
6. The precursor composition of claims 2-5 wherein the buffering anion is acetate at a concentration ranging from about 0.3 to about 125 mEq/L.

7. The precursor composition of claim 2-5 wherein the buffering anion is lactate at a concentration ranging from about 0.3 to about 125 mEq/L.

8. The precursor composition of claims 1-7 wherein the physiologically-acceptable cation is selected from a group consisting of hydrogen, sodium, potassium, calcium, magnesium, and combinations thereof.

9. The precursor composition of claims 1-8, further comprising a sugar selected from glucose, a poly(glucose), and fructose at a concentration of less than about 2,700 g/L.

10. The precursor composition of claims 1-9 wherein the citrate is in the form of at least one of citric acid and a salt thereof selected from a group consisting of sodium dihydrogen citrate, disodium hydrogen citrate, trisodium citrate, trisodium citrate dihydrate, potassium dihydrogen citrate, dipotassium hydrogen citrate, calcium citrate, and magnesium citrate; wherein the buffering anion acetate is in the form of at least one of acetic acid and a salt thereof selected from a group consisting of sodium acetate, sodium acetate trihydrate, potassium acetate, calcium acetate, calcium acetate monohydrate, magnesium acetate, and magnesium acetate tetrahydrate; and wherein the buffering anion lactate is in the form of at least one of lactic acid and a salt thereof selected from a group consisting of sodium lactate, potassium lactate, calcium lactate and magnesium lactate trihydrate.

11. The precursor composition of claims 1-10 wherein the water meets or exceeds the purity requirements established by the Association for the Advancement of Medical Instrumentation (AAMI) for dialysate, and all other components have at least United States Pharmacopeia (USP)-grade purity.

12. The precursor composition of claims 1-11 having a pH ranging from about 1 to about 6.5 at a temperature of about 15°C to about 40°C.

13. The precursor composition of claims 1-12 comprising chloride at a concentration ranging from about 2,000 to about 5,000 mEq/L; citrate at a concentration ranging from about 70 to about 150 mEq/L; acetate at a concentration ranging from about 0.3 to about 125 mEq/L; at least one physiologically-acceptable cation selected from hydrogen, sodium at a concentration ranging from about 2,000 to about 5,000 mEq/L, potassium at a concentration of less than about 250 mEq/L, calcium at a concentration of less than about 250 mEq/L, and magnesium at a concentration of less than about 100 mEq/L; and glucose at a concentration of less than about 2,700 g/L, where the composition at least meets the AAMI standard set for dialysate.

14. The precursor composition of claims 1-13 further comprising iron.

15. The precursor composition of claims 1-13 further comprising one or more trace elements.

16. A buffered dialysate composition comprising treated water; chloride at a concentration ranging from about 20 to about 200 mEq/L; citrate at a concentration ranging from about 0.5 to about 30 mEq/L; a buffer; base including bicarbonate; and at least one physiologically-acceptable cation.

17. The dialysate composition of claim 16 wherein the buffer comprises a buffering anion selected from acetate and lactate at a concentration ranging from about 0.01 to about 4.5 mEq/L;

18. The dialysate composition of claims 16-17 wherein the base further includes at least one of carbonate, lactate salt, citrate salt, and acetate salt at a concentration ranging from about 25 to about 45 mEq/L.

19. The dialysate composition of claims 16-18 wherein the physiologically-acceptable cation is selected from a group consisting of hydrogen, sodium, potassium, calcium, magnesium, and combinations thereof.

20. The dialysate composition of claims 16-19, further comprising a sugar selected from glucose, poly(glucose) and fructose, at a concentration of less than about 45 g/L.

21. The dialysate composition of claim 16-20 wherein the water meets or exceeds the purity requirements established by AAMI for dialysate and all other components have at least USP-grade purity.

22. The dialysate composition of claims 16-21 wherein the pH is about 5 to about 8.5 at a temperature of about 25°C to about 40°C.

23. The dialysate composition of claims 16-22 further comprising iron.

24. The dialysate composition of claims 16-22 further comprising one or more trace elements.

25. The dialysate composition of claims 16-24 comprising chloride at a concentration ranging from about 60 to about 120 mEq/L; citrate at a concentration ranging from about 2 to about 3 mEq/L; acetate at a concentration ranging from about 0.2 to about 0.5 mEq/L; bicarbonate at a concentration ranging from about 25 to about 45 mEq/L; at least one physiologically-acceptable cation selected from hydrogen,

sodium at a concentration ranging from about 70 to about 150 mEq/L, potassium at a concentration of less than about 5 mEq/L, calcium at a concentration of less than about 5 mEq/L, and magnesium at a concentration of less than about 2 mEq/L; and glucose at a concentration of less than about 45 g/L, where the composition meets or exceeds the AAMI-quality standard set for dialysate.

26. A method of forming a dialysate precursor composition comprising mixing treated water, chloride, citrate, at least one buffering anion selected from acetate and/or lactate, and at least one physiologically-acceptable cation to provide a composition having chloride at a concentration ranging from about 1,000 to about 7,000 mEq/L, citrate at a concentration ranging from about 20 to about 900 mEq/L, and at least one buffering anion selected from acetate and lactate at a concentration ranging from about 0.01 to about 150 mEq/L.

27. The method of claim 26 comprising citrate at a concentration ranging from about 70 to about 150 mEq/L.

28. The method of claim 26 wherein the buffering anion is acetate at a concentration ranging from about 0.3 to about 125 mEq/L.

29. The method of claim 26 wherein the buffering anion is lactate at a concentration ranging from about 0.3 to about 125 mEq/L.

30. The method of claim 26 wherein the physiologically-acceptable cation is selected from a group consisting of hydrogen, sodium, potassium, calcium, magnesium, and combinations thereof.

31. The method of claim 26, further comprising mixing the dialysate precursor with a sugar selected from glucose, poly(glucose) and fructose, at a concentration of less than about 2,700 g/L.

32. The method of claim 26 wherein the citrate is in the form of at least one of citric acid or a salt thereof selected from a group consisting of sodium dihydrogen citrate, disodium hydrogen citrate, trisodium citrate, trisodium citrate dihydrate, potassium dihydrogen citrate, dipotassium hydrogen citrate, calcium citrate, and magnesium citrate.

33. The method of claim 26 wherein the buffering anion acetate is in the form of at least one of acetic acid or a salt thereof selected from a group consisting of sodium acetate, sodium acetate trihydrate, potassium acetate, calcium acetate, calcium acetate monohydrate, magnesium acetate, and magnesium acetate tetrahydrate.

34. The method of claim 26 wherein the buffering anion lactate is in the form of at least one of lactic acid or a salt thereof selected from a group consisting of sodium lactate, potassium lactate, calcium lactate and magnesium lactate trihydrate.

35. The method of claim 26 further comprising mixing iron.

36. The method of claim 26 further comprising mixing one or more trace metals.

37. The method of claim 26, further comprising mixing the dialysate precursor composition with treated water, wherein the treated water meets or exceeds the purity requirements established by AAMI for dialysate, and all other components have at least USP-grade purity.

38. The method of claim 26 comprising chloride at a concentration ranging from about 2,000 to about 5,000 mEq/L; citrate at a concentration ranging from about 70 to about 150 mEq/L; acetate at a concentration ranging from about 0.3 to about 125 mEq/L; at least one physiologically-acceptable cation selected from hydrogen, sodium at a concentration ranging from about 2,000 to about 5,000 mEq/L, potassium at a concentration of less than about 250 mEq/L, calcium at a concentration of less than about 250 mEq/L, magnesium at a concentration of less than about 100 mEq/L; and dextrose at a concentration of less than about 2,700 g/L, where the composition meets or exceeds the AAMI-quality standard set for dialysate.

39. A method of forming a buffered dialysate composition comprising mixing a dialysate precursor composition with an aqueous bicarbonate-containing solution, the dialysate precursor composition comprising treated water, chloride, citrate, at least one buffering anion selected from acetate and lactate, and at least one physiologically-acceptable cation to provide a dialysate composition having chloride at a concentration ranging from about 44 to about 143 mEq/L, citrate at a concentration ranging from about 1.5 to about 30 mEq/L, and at least one buffering anion selected from acetate and lactate at a concentration ranging from about 0.01 to about 3.6 mEq/L.

40. The method of claim 39 wherein the bicarbonate-containing solution further comprises a base selected from a group consisting of carbonate, lactate, citrate, and acetate at a concentration ranging from about 25 to about 45 mEq/L.

41. The method of claim 39 wherein the physiologically-acceptable cation is selected from a group consisting of hydrogen, sodium, potassium, calcium, magnesium, and combinations thereof.

42. The method of claim 39 wherein the composition further comprises a sugar selected from dextrose, icodextrin, and fructose at a concentration of less than about 45 g/L.

43. The method of claim 39 wherein the composition further comprises iron.

44. The method of claim 39 wherein the composition further comprises one or more trace metals.

45. The method of claim 39 wherein the dialysate composition comprises chloride at a concentration ranging from about 44 to about 143 mEq/L; citrate at a concentration ranging from about 1.5 to about 4.5 mEq/L, the buffering anion acetate at a concentration ranging from about 0.01 to about 3.6 mEq/L; bicarbonate at a concentration ranging from about 25 to about 45 mEq/L; at least one physiologically-acceptable cation selected from hydrogen, sodium at a concentration ranging from about 69 to about 188 mEq/L, potassium at a concentration of less than about 5 mEq/L, calcium at a concentration of less than about 5 mEq/L, and magnesium at a concentration of less than about 2 mEq/L; and glucose at a concentration of less than about 45 g/L; where the composition meets or exceeds the AAMI-quality standards set for dialysate.

46. A composition prepared according to the method of claim 26.

47. A composition prepared according to the method of claim 39.

48. An aqueous acid-concentrate composition comprising water, chloride at a concentration of about 1,000 to about 7,000 mEq/L; citrate at a concentration ranging from about 20 to about 900 mEq/L; and sufficient physiologically-

acceptable cations to provide for a neutral composition, where the composition has a pH of less than 4, and does not contain any of acetate, bicarbonate or lactate.

49. The composition of claim 48 further comprising iron.

50. The composition of claim 48 further comprising at least one trace element.

51. A peritoneal dialysate composition comprising sterile water, citrate at a concentration of about 0.5-6 mEq/L; chloride at a concentration of about 20-200 mEq/L; bicarbonate at a concentration of about 5-100 mEq/L assuming all carbonate-containing species are in the bicarbonate form, glucose at a concentration of about 10-100 g/L; and a sufficient number of physiologically-acceptable cations to neutralize all of the citrate, chloride, bicarbonate, and any other anionic species that may be present in the composition.

52. The composition of claim 51 further comprising iron.

53. The composition of claim 51 further comprising at least one trace element.

54. A method for performing dialysis comprising combining a first solution with a second solution to form dialysate, and performing hemodialysis with the dialysate, the first solution comprising citrate, buffer, and water, the second solution comprising bicarbonate and water.

55. The method of claim 54 wherein the first solution comprises iron.

56. The method of claim 54 wherein the first solution comprises at least one trace element.